Eco-Care

Technologies Inc.

August 15, 2005

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Director, Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Ave., SW
Room 4008-So., Ag Stop 0268
Washington, DC 20250

SUBJECT: NOP Sunset Review - Docket number: TM-04-07

Dear Mr. Neal:

I am providing you with my comments on the NOP Sunset Review – Docket Numer TM-04-07.

§205.601 Synthetic substances allowed for use in organic crop production

b) (1) Herbicides, soap-based-for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops

Soap-based herbicides should continue to be allowed. Soaps are based on naturally occurring fatty acids, they degrade rapidly and are virtually non-toxic.

The only by-product in the manufacture of fatty acid soaps is water. Fatty acids occur naturally and are not harmful to the environment. In fact fatty acids and fatty acid derivatives are important nutrient sources for plants and animals. Living organisms, including humans, have a physiological requirement for fatty acids.

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Salts of fatty acids are metabolized naturally in the environment. Fatty acids are part of the normal metabolic make up of cells and the enzymatic pathways for their degradation and synthesis are well established in the literature. In plants, the fatty acids are mainly degraded by oxidation pathways, especially α and β oxidation, and eventually released as CO_2 and water.

The normal route of metabolism of fatty acid compounds ingested by animals, results in the release of free fatty acids within the stomach regardless of the lipid ingested. For instance, ingestion of coconut oil results in release of C_8 fatty acid in the gut. The fatty acids are transported in the body via the lymph system or blood stream. They are eventually metabolized into storage compounds for later use or used as an energy source with eventual release of CO_2 and water. Ingestion of the insecticide will follow the same metabolic pathways as other fatty acid compounds and the $C_{18:1}$ fatty acid will be indistinguishable from endogenous $C_{18:1}$ fatty acids.

"The first soap salts product with pesticidal uses was registered in 1947." (US EPA; 1992)¹ As a consequence, the toxicology of this active ingredient is well known. "Soaps generally have low toxicity to humans and, there is no reason to expect that pesticide use in accordance with use directions would constitute any significant hazard." (US EPA, 1992)

Fatty acid soaps break down rapidly in the environment. The initial step in the breakdown process of the mineral salts of fatty acids is the division of the salt into the mineral and fatty acid ions. Plants, soil microorganisms or animals will utilise the resulting mineral and fatty acids to meet their nutritional requirements. The US EPA has evaluated soap salts and published a reregistration eligibility document on this active ingredient. In this document it was concluded that "residues from the pesticide uses are not likely to exceed levels of naturally occurring or intentionally added fatty acids in commonly eaten foods, the Agency believes the risks to applicators and consumers of treated foods are negligible." (US EPA; 1992) In addition "(s)tudies submitted to the Agency indicate that the half-life of these fatty acids is approximately less than one day (MRID 00157476). As can be expected, there is very rapid microbial degradation of fatty acids in soil. Fatty acids and their salts are excellent substrate for microbial growth, serving both as carbon sources, and as energy sources. The active ingredient cannot totally dissipate from soil, because there is a natural content of fatty acids in soil resulting from plant metabolism and by formation by microbial organisms.....Therefore, the Agency believes that these chemicals, when used as directed, will not persist in the environment." (US EPA; 1992)

Fatty acids occur in all soils due to their presence in soil microorganisms and decaying organic material. Fatty acids are common constituents in every living cell and are normally used for structural integrity of cells, as building blocks for more complex compounds and as a high energy food source. Endogenous fatty acids consist of a wide variety of chain lengths of both saturated and unsaturated fatty acids. Exogenous fatty acids are metabolized

by the same pathways as the endogenous fatty acids. Soil microorganisms rapidly metabolize both endogenous and exogenous fatty acids, therefore, exogenous fatty acids are biodegraded rapidly, i.e. in 1 - 2 days. Fatty acids are not residual enough to be taken up by second generation plants. The natural occurrence and rapid metabolism of fatty acids in soil cause them to pose no threat to drinking water.

1. US EPA. 1992. Re-registration Eligibility Document (RED) Soap Salts. US EPA Report #540/RS-92-231.

Fatty acid soaps are also compatible with a system of sustainable agriculture and with organic farming and handling because there are no harmful residual effects on the environment and because they are derived from natural souces for which there are already methods of degradation and utilization in the eocsystem.

e) (6) Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils.

Synthetic oils should be prohibited because there are naturally occurring alternatives. Vegetable oils are effective dormant, suffocating and summer oils.

While narrow range horticultural oils may pose little threat of introducing harmful compounds to the organic farm, the refining of these oils produces harmful byproducts. Polycyclic aromatic compounds (PACs) and other cyclic compounds such as benzene, xylene and toluene are removed from the petroleum distillates in the refining process. Many of these compounds are known or suspected carcinogens.² Vegetable oils are non-synthetic and produce no such byproducts. There are insecticidal/fungicidal oils on EPA's minimum risk pesticide list [40CFR 152.25(f)], eg. cottonseed oil, soybean oil. In addition there are registered products containing canola oil and soybean oil as the active ingredients, Reg. No. 67702-4, 57538-11 and 72061-1.

2. Mackerer, C.R., Griffis, L.C., Grabowski, J.S. Jr., Reitman, F.A. 2003. *Petroleum Mineral Oil Refining and Evaluation of Cancer Hazard*. Applied Occupational and Environmental Hygiene, **18**(11) pp 890-901.

e) (7) Soaps, insecticidal

Insecticidal soaps should continue to be allowed. Soaps are based on naturally occurring fatty acids, they degrade rapidly and are virtually non-toxic.

The only by-product in the manufacture of fatty acid soaps is water. Fatty acids occur naturally and are not harmful to the environment. In fact fatty acids and fatty acid derivatives are important nutrient sources for plants and animals. Living organisms, including humans, have a physiological requirement for fatty acids.

Potassium salts of fatty acids are metabolized naturally in the environment. Potassium is a macronutrient essential to plant, animal and microbial growth. Fatty acids are part of the normal metabolic make up of cells and the enzymatic pathways for their degradation and synthesis are well established in the literature. In plants, the fatty acids are mainly degraded by oxidation pathways, especially α and β oxidation, and eventually released as CO_2 and water.

The normal route of metabolism of fatty acid compounds ingested by animals, results in the release of free fatty acids within the stomach regardless of the lipid ingested. For instance, ingestion of coconut oil results in release of C_8 fatty acid in the gut. The fatty acids are transported in the body via the lymph system or blood stream. They are eventually metabolized into storage compounds for later use or used as an energy source with eventual release of CO_2 and water. Ingestion of the insecticide will follow the same metabolic pathways as other fatty acid compounds and the $C_{18:1}$ fatty acid will be indistinguishable from endogenous $C_{18:1}$ fatty acids.

"The first soap salts product with pesticidal uses was registered in 1947." (US EPA; 1992) As a consequence, the toxicology of this active ingredient is well known. "Soaps generally have low toxicity to humans and, there is no reason to expect that pesticide use in accordance with use directions would constitute any significant hazard." (US EPA, 1992)

Fatty acid soaps break down rapidly in the environment. The initial step in the breakdown process of the potassium salts of fatty acids is the division of the salt into potassium and fatty acid ions. Plants, soil microorganisms or animals will utilise the resulting potassium and fatty acids to meet their nutritional requirements. The US EPA has evaluated soap salts and published a reregistration eligibility document on this active ingredient. In this document it was concluded that "residues from the pesticide uses are not likely to exceed levels of naturally occurring or intentionally added fatty acids in commonly eaten foods, the Agency believes the risks to applicators and consumers of treated foods are negligible." (US EPA; 1992) The potassium salts of fatty acids active ingredient has been established as exempt from the requirement of a tolerance effective 1982, by the US EPA. In addition "(s)tudies submitted to the Agency indicate that the half-life of these fatty acids is approximately less than one day (MRID 00157476). As can be expected, there is very rapid microbial degradation of fatty acids in soil. Fatty acids and their salts are excellent substrate for microbial growth, serving both as carbon sources, and as energy sources. The active ingredient cannot totally dissipate from soil. because there is a natural content of fatty acids in soil resulting from plant metabolism and by formation by microbial organisms.....Therefore, the Agency believes that these chemicals, when used as directed, will not persist in the environment." (US EPA; 1992)

The potassium salts of fatty acids active ingredient in this insecticide product will not adversely affect the environment. Potassium is a mineral which

constitutes 2.4% of the earth's crust. It is an essential macronutrient for plants, animals and microorganisms. Fatty acids occur in all soils due to their presence in soil microorganisms and decaying organic material. Fatty acids are common constituents in every living cell and are normally used for structural integrity of cells, as building blocks for more complex compounds and as a high energy food source. Endogenous fatty acids consist of a wide variety of chain lengths of both saturated and unsaturated fatty acids. Exogenous fatty acids are metabolized by the same pathways as the endogenous fatty acids. Soil microorganisms rapidly metabolize both endogenous and exogenous fatty acids, therefore, exogenous fatty acids are biodegraded rapidly, i.e. in 1 - 2 days. Fatty acids are not residual enough to be taken up by second generation plants. The natural occurrence and rapid metabolism of fatty acids in soil cause them to pose no threat to drinking water.

Fatty acid soaps are also compatible with a system of sustainable agriculture and with organic farming and handling because there are no harmful residual effects on the environment and because they are derived from natural souces for which there are already methods of degradation and utilization in the eocsystem.

i) (1) coppers, fixed

Fixed coppers should continue to be allowed. Copper occurs naturally in the environment and is an essential micronutrient for some organisms.

i) (6) Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils.

Synthetic oils should be prohibited because there are naturally occurring alternatives. Vegetable oils are effective dormant, suffocating and summer oils.

While narrow range horticultural oils may pose little threat of introducing harmful compounds to the organic farm, the refining of these oils produces harmful byproducts. Polycyclic aromatic compounds (PACs) and other cyclic compounds such as benzene, xylene and toluene are removed from the petroleum distillates in the refining process. Many of these compounds are known or suspected carcinogens.² Vegetable oils are non-synthetic and produce no such byproducts. There are insecticidal/fungicidal oils on EPA's minimum risk pesticide exempted products list [40CFR 152.25(f) (1)], eg. cottonseed oil, soybean oil. In addition there are registered products containing canola oil and soybean oil as the active ingredients, Reg. No. 67702-4, 57538-11 and 72061-1.

2. Mackerer, C.R., Griffis, L.C., Grabowski, J.S. Jr., Reitman, F.A. 2003. Petroleum Mineral Oil Refining and Evaluation of Cancer Hazard. Applied Occupational and Environmental Hygiene, **18**(11) pp 890-901.

m) (1) EPA List 4-Inerts of Minimal Concern

EPA List 4 inerts should continue to be allowed for use. These inerts have been carefully screened by the EPA and deemed to be of minimal concern to humans and the environment. Without these inerts it would be exceedingly difficult to create stable, effective formulations for weed, pest and disease control.

Best wishes,

Catherine Stewart

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